A qualitative exploration of the experience of using an above-knee prosthesis with a microprocessor knee

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Research assignment in partial fulfilment of the requirements of

Master of Human Rehabilitation Studies

at Stellenbosch University

Centre for Disability and Rehabilitation Studies

Faculty of Medicine and Health Sciences

Stellenbosch University

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December 2021

Declaration

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Abstract

Background: Modern technology has allowed for many advancements in prosthetic knees. One such advancement is microprocessor-controlled knees. Quantitative research has shown functional advantages amongst users of microprocessor knees. However, the user experiences of these knees have not been widely explored.

Objective: The study aimed to explore and describe the experience of using and obtaining an above-knee prosthesis with a microprocessor knee.

Study design: This study was qualitative descriptive in design.

Methods: Six participants who used prostheses with microprocessor knees were purposively sampled. Data were collected through semi-structured interviews using video-calls. An inductive thematic analysis led to the identification of five themes.

Results: Identified themes were: A life of quality – "life-changing"; Functional ability – "the beauty is that it helps you perform properly"; Safety – "a few stumbles but every time the knee catches me"; Limitations – "sometimes the mechanics are a little bit slow"; and Obtaining a microprocessor knee. Participants felt that the microprocessor knee decreased their disability and helped to normalize them. They were more functional with the protheses and positive about the safety features of the microprocessor knee. Obtaining funding for the microprocessor knee was typically a lengthy process and raised important questions around the ethical dilemma of cost versus benefit.

Conclusion: Using the MPKs have improved the lives of participants in many ways. Being more aware of these benefits may assist practitioners in offering the appropriate prescription and funding motivation for future users. The cost versus benefit conundrum around prescribing microprocessor knees must be further explored especially in low- and middle-income countries.

Keywords

Microprocessor knee, experiences, transfemoral amputation, South Africa, life-changing, performance, safety, function, satisfaction

Abstrak

Agtergrond: Moderne tegnologie het baie vooruitgang in prostetiese knieë moontlik gemaak. Die mikroprosessorbeheerde knie is ‘n voorbeeld hiervan. Kwantitatiewe navorsing het funksionele voordele onder gebruikers van mikroprosessorknieë getoon. Gebruikerservarings van hierdie knieë is egter nie wyd ondersoek nie.

Doelwit: Die doel van hierdie studie was om die ervaring rakende die verkryging en gebruik van transfemorale prosteses met mikroprosessorknieë te ondersoek en te beskryf.

Studie-ontwerp: ‘n Kwalitatiewe, beskrywende studie ontwerp is gevolg.

Metodes: Ses deelnemers wat prostesis met mikroprosessor kniee gebruik is doelgerig gekies. Data is versamel deur middel van semi-gestruktureerde onderhoude met behulp van ‘n video-oproep. Induktiewe tematiese analise het gelei tot die identifisering van vyf temas.

Bevindinge: Geïdentifiseerde temas was: 'n Lewe van kwaliteit – "Lewensveranderend"; Funksionele vermoë – "die prag is dat dit jou help om behoorlik te presteer"; Veiligheid – “die knie vang my elke keer as ek struikel", Beperkings "soms is die meganika ‘n bietjie stadig"; en die verkryging van 'n mikroprosessorknie. Deelnemers het gemeen dat die mikroprosessorknie hul gestremdheid verminder en gehelp het om hul ’n meer normale lewe te laat lei. Hulle was meer funksioneel met die prostese en positief oor die veligheidskenmerke van die knie. Die verkryging van finansiering vir die mikroprosessorknie was gewoonlik ‘n lang proses en het vrae laat ontstaan rondom die etiese dilemma van koste versus voordele.

Gevolgtrekking: Die gebruik van mikroprosessorknieë het die lewens van deelnemers op baie maniere bevoordeel. As daar meer bewustheid van hierdie voordele is, mag dit praktisyns help om toepaslike voorskrif- en finansieringsmotiverings vir toekomstige gebruikers te bepaal. Die koste versus voordele konundrum rondom the voorskryf van mikroprosessor kniee moet verder ondersoek word, veral in lae en middel inkomste lande.

Sleutelwoorde

Mikroprosessorknie, ervarings, transfemorale amputasie, Suid-Afrika, lewensveranderend, prestasie, veiligheid, funksie, tevredenheid

Acknowledgements

Throughout the writing of this dissertation, I have received a great deal of support and assistance.

Firstly, I would like to thank all participants, who without every valuable insight and story shared, this project would not have been possible.

I would like to thank my supervisor, Dr Surona Visagie, for her continuous support. Your expertise allowed me to sharpen my thinking, and your invaluable assistance was a key factor in completing this research study I wholeheartedly appreciate your patience and encouragement. Your professional conduct allowed for easy communication and much needed honest feedback.

I would also like to thank my co-supervisor, Ms Elzbeth Pienaar. Your guidance brought to light vital aspects that allowed for further thinking and questioning, enabling me to produce higher quality work.

Thank you to all my family and friends for your support throughout the past two years for wise counsel and a sympathetic ear on so many occasions, no matter how tough it might have been.

Abbreviations

AKA:	Above-knee amputation
HREC:	Health Research Ethics Committee
IP:	Intelligent prosthesis
IRB:	Institutional Review Board
LMIC:	Lower middle-income countries
MPK:	Microprocessor knee
MRC:	Medical Research Council
NHREC:	National Health Research Ethics Council
NMPK:	Non-microprocessor knee
OHRP:	Office of Human Research Protections
RAF:	Road Accident Fund
WHO:	World Health Organization
HIC:	High Income Country

Table of Contents

1. Background

Losing a limb is a life-changing event and causes physical and emotional challenges when returning to preamputation life roles (Sahu, Sagar, Sarkar & Sagar, 2016). Mobility and physical function post lower limb amputation are often addressed by providing a prosthesis (Marzen-Groller, Tremblay, Kaszuba, Girodo, Swavely, Moyer et al., 2008; Webster, Hakimi, Williams, Turner, Norvell & Czerniecki, 2012; Wyss, Lindsay, Cleghorn & Andrysek, 2015). However, obtaining a prosthesis does not guarantee successful mobility (Condie, Mcfayden, Treweek & Whitehead, 2011). Research conducted in high income countries shows that between 75% and 87% of persons with an above-knee amputation used their prosthesis on a daily basis (Hagberg & Branemark, 2001; Puhalski, Taylor & Poulin, 2008; Tezuka, Chin, Takase, Azuma, Nakatsuka, Fujie et al., 2015). On the contrary, Pienaar and Visagie (2019) conducted a South African based study and found that 42% of participants with an above-knee amputation used their prosthesis daily. Such differences may be the result of a poor fitting prosthesis, inappropriate componentry for physical and environmental demands, or poor aesthetics. (Andrysek, 2010). Unsuitable prosthetic componentry might be a reason for poor or nonuse of prothesis although this aspect is seldom researched (Karn et al 2019).

The prosthetic knee is an important component of the above knee prosthesis. Prosthetic knees should mimic the complex characteristics of the human knee, such as shock absorption, with a focus on stance phase stability and swing phase mobility (Bayram, 2013; Hoffman, 2019). In selecting the prosthetic knee component, the prosthetist will consider factors related to the cause of amputation (Mundell, Kremers, Visscher, Hoppe & Kaufman, 2016), physical abilities (Geertzen, Van der Linde, Rosenbrand, Conradi & Deckers, 2014; Mundell et al., 2016), life roles, and type of employment, as well as the availability of prosthetic rehabilitation, prosthetic support services, and the environment in which the person functions (Kam, Kent, Khodaverdian, Daiter, Njelesani, Cameron et al., 2015). The prosthetic componentry selected

must fit the user's physical abilities, their chosen functional tasks and environmental demands for optimal prosthetic performance to occur (Andrysek, 2010; Kam et al., 2015; Pienaar & Visagie 2019).

A range of MPKs with different functions are available and must be appropriately prescribed (Morgenroth, 2013). One cannot expect to compare different MPKs and receive the same outcomes. Prospective users must be evaluated thoroughly before a prescription decision is made (Morgenroth, 2013).

Quantitative and qualitative studies comparing user outcomes between MPKs and NMPKs have shown enhanced physiological body functions such as lower energy expenditure and oxygen cost, increased mobility and a more natural gait pattern, higher standards of safety, stability and control over uneven surfaces, a more positive social aspect by increased participation in the individual's environment and higher quality of life (Hafner & Askew, 2015; Kannenberg, Zacharia & Probsting, 2014; Stevens & Wurdeman, 2019; Squella, Kannenberg & Benetti, 2018; Şen, Aydın, Buğdaycı & Kesiktaş, 2020; Sawers & Hafner, 2013; Mileusnic, et al, 2019). The safety aspect is important as there are multiple reports of decreased falls, stumbles and fear or falling, contributing towards a higher level of prosthetic use. Prosthetic users also reported improvement in stair (stairs can be climbed foot over foot) and hill descent, a greater ability to multitask and increased satisfaction when using MPKs (Squella, Kannenberg & Benetti, 2018). Functionally, the MPK allows for dynamic management during the gait cycle, whereas mechanical knees are free swinging and give the user less control. Other documented benefits of the MPK are the ability to walk at varying speeds and longer walking distances (Hafner et al., 2007). While earlier authors were not in agreement that MPKs offer functional and participation advantages to above-knee prosthetic users (Berke, 2013), clinical recommendations based on later studies show clear benefits, as summarized by Stevens and Wurdeman (2019).

However, as with anything, there are also disadvantages to MPKs although not widely documented. Aside from the hefty price of this technology, it is also heavier and larger than NMPKs and for this reason does not pair well with a cosmesis (a potentially important factor in cultural settings in LMIC). It has a battery that needs frequent charging and may not work well in certain environments such as dust, water, excess temperatures and chemicals and it requires an experienced, trained practitioner as well as a commitment from the user to learn how to manage and look after the knee correctly (Crowe, et al. 2019). The costs depend on the specific knee and can range from between R60 000 to over a million rand.

The high cost of MPKs is mentioned as a potential harm in the clinical practice guidelines by Stevens and Wurdeman (2019). However, studies have suggested that the high initial cost of the MPK might be set off by future financial advantages such as accessing employment (Chen, Hanson, Chaturvedi & Mattke, 2018; Kuhlmann, Kruger, Seidinger & Hahn, 2020; Donnelley, et al. 2021).

Not all prosthetic users will benefit from a MPK. Berke (2013) and Taylor (2020) emphasise the importance of understanding how MPKs impact the life experiences of individual users to assist with the prescription of MPKs.

1.1 Use of microprocessor prosthetic knees in South Africa

As a LMIC, South Africa has a dual health care system (public and private). The public health care system provides care for more than 80% of the country's population. MPKs are not issued in the public sector and is only really a consideration in the private sector if the user has a RAF settlement or is willing to pay cash. Although no figures are available, we can assume that a very small part of above-knee prosthetic users in South Africa currently receive MPKs.

Aside from the cost limitation, there are other barriers that limit their use and prescription such as limited access to prosthetists, prosthetic centres and rehabilitation, long travel distances

coupled with transport barriers, shortage of human and other resources (Ennion & Manig, 2019; Pienaar & Visagie, 2019). These barriers negatively impact the use of advanced knee designs such as MPKs, because these knees require maintenance to ensure that they are in perfect working order and users would require training in their use (Wyss et al., 2015). In additon the environmental factors that might hamper use of MPKs as described earlier and the need of access to electricity to charge the batteries might hamper use in SA and other LMICs. No research related to these aspects could be identifed.

In summary, studies from high income countries show that MPKs hold functional advantages over other types of knees; however, no studies on MPKs in Africa could be identified. The effect of the reported enhanced function and mobility on the lived experiences of MPK users has also not been explored (Taylor, 2020). South African practitioners do not often consider MPKs due to financial and maintenance constraints. This study seeks to hear from South Africans who use MPKs and explore their experiences around MPKs. The findings might help identify individuals who might benefit from an MPK and be useful to prosthetists when motivating for this technology's funding approval.

Thus, the study aimed to explore and describe the experiences of individuals using an above-knee prosthesis with an MPK.

2. Methods

2.1 Study design

This study used a descriptive qualitative methodology to explore participants' experiences when using a MPK. Descriptive qualitative research seeks to learn from participants and interpret findings while staying close to the data. Its value lies in the ability to provide service providers with practical guidance on which to base future action (Bradshaw et al 2017).

2.2 Population and sampling

Individuals older than 18 years fitted with a transfemoral prosthesis with an MPK at one of three conveniently selected private prosthetic practices in Cape Town, South Africa, before 31 January 2020, formed the study population. Individuals with additional impairments (such as multiple amputations, traumatic brain injury, blindness, deafness), or through-knee amputations were excluded as these variables might influence experiences with the MPK.

The owners of the three practices purposively sampled and recruited participants. During sampling, practice owners ensured that men and women from all age groups (above 18) with amputations for vascular and non-vascular causes were included as well as those that were first time users or users with experience in MPKs. Six persons participated in the study.,. Provisional analysis of current study data showed no new themes emerged after six interviews; data saturation was, therefore, reached and data collection stopped.

2.3 Recruitment

The practice owners called or emailed the sampled individuals, introduced them to the study, obtained provisional consent, and obtained permission to share their contact details with the author. One person did not respond to the email; therefore, another individual was sampled instead. The author contacted those who provisionally consented, explained the study in detail, obtained their email addresses, and set up a time and date for a video call to collect data. The

informed consent document (see Appendix A) was sent to the participants and returned to the author via email. If participants had questions on reading the consent form, they could contact the author for clarification, but no-one did.

2.4 Data collection

Data were collected through semi-structured individual interviews using video calls. Semi-structured interviews allowed the participants to speak freely and follow different trains of thought. It also gave the author the freedom to shift to topics introduced by the participants (O'Leary, 2017). Interviews were audio-recorded and lasted between 22 minutes and an hour. All the participants were comfortable to be interviewed in English. Interviews were guided by an interview schedule (see Appendix A) that was tested during a pilot interview. The interview covered the following broad topics:

- Life and functionality with the MPK
- Feelings about the MPK
- Funding of the MPK

No changes were made to the methods based on the pilot interview. Thus, data from the pilot interview were included in the main study.

2.5 Data analysis

Data were analysed thematically through an inductive process without the use of software. The author familiarised herself with the data by transcribing the data, reading the transcripts, listening to the audiotapes, and highlighting pertinent information. The data were then reduced into smaller segments of meaning, which, in turn, were coded. Thereafter, themes were identified by organising similar codes together. Themes were reviewed based on the following questions: Does it make sense? Do the data support it? Is too much being fitted into one theme?

Are the themes mutually exclusive, or do they overlap? Once the author was satisfied with the answers, the final themes were defined (Maguire & Delahunt, 2017).

2.6 Ethical considerations

This research study was registered with the Health Research Ethics Committee of Stellenbosch University (S19/10/248) (see Appendix C). The following broad ethical aspects were considered:

- **Beneficence and non-maleficence.** The research was conducted in a manner that caused no physical harm to participants. A possible side effect of the study might have been emotional distress. A counsellor was available, but her input was not required. Confidentiality was maintained throughout the course of the research study. No names or other identifying particulars will be used in this thesis or any dissemination from the study. Data will be kept securely and destroyed after five years (Barrow, Brannan & Khandhar, 2019; DOH, 2015). Participants received 1GB of data for their time.
- **Distributive justice.** The study did not exclude anybody based on gender, race, or religious beliefs. All participants had the same opportunity to share their experiences (DoH, 2015). The prosthetists who assisted with participant identification do not stand to benefit from the study, as participant names were not disclosed. The MPKs were ordered from various third-party suppliers.
- **Respect for persons.** Written informed consent was obtained from each participant. No participant was coerced into participating, and they did not have to answer questions that they were uncomfortable with. Participants were also made aware that they could stop participating at any time without fear of negative consequences (DoH, 2015).

2.7 Trustworthiness

The author strove to ensure trustworthiness through credibility, transferability, dependability, and confirmability. Credibility was sought through purposive sampling, seeking data saturation, collaborating with my supervisor during data analysis and providing rival opinions where it occurred. Furthermore, the author provided a detailed description of the methods and participants' demographic details so that potential users of the findings can decide if it can be transferred to their context. Dependability and confirmability were sought by describing the methods sequentially to allow for repetition. The author believes that a clear thought trail was demonstrated, and data interpretations are transparent and consistent. Verbatim quotes to elucidate findings are included within the ambit of this thesis. The author is a prosthetist by profession and has her own opinions about MPKs. During data collection, analysis, and write up, the author reflected on her thoughts and opinions to ensure subjectivity (Mabuza, Govender, Ogunbanjo & Mash, 2014).

2.8 Study limitations

The original study proposal called for in-person interviews. This had to be revised due to COVID-19 pandemic restrictions. Data collection via video call introduced the following limitations:

- **Signal/Internet connectivity.** During interviews, connectivity was sometimes lost. Consequently, sentences were repeated. In some instances, video lag and/or poor sound was experienced. These challenges negatively impacted the flow of the interviews. In the worst cases, words were unclear and could not be transcribed.
- **Battery power and load shedding.** To ensure that interviews were not interrupted by flat batteries, interviews had to be scheduled and sometimes rescheduled to ensure electricity availability to charge mobile phones.

Identifying study participants:

- Prosthetists who prescribed the MPK to sample participants introduced bias as they might have selected those who experienced the MPK as positive. Participants might also have felt obliged to participate in the study due to their relationship with the prosthetist. However, the author had no other way of identifying possible participants as no database on MPK users are available in South Africa. The author also ensured that participants are aware that she had no professional or personal connection to the prosthetists beyond being in the same profession.

- The study population was small, with a limited choice of participants as MPKs are rarely prescribed in South Africa. Thus, even though data saturation was achieved, further studies are needed to see if the findings hold true for other populations.

3. Findings

Demographic details: Participants' ages ranged from 25 to 75 (see Table 1 below). Amputations were done for vascular reasons or following trauma. One woman participated in the study.

Table 1. Demographic details of participants

Pseudonym	Age	Gender	Previously used mechanical knee	Type of MPK	Cause of amputation	Employment	Funding
Jeannot	73	Man	Yes	Genium	Vascular	Retired	German health insurance
Ettiene	34	Man	Yes	Genium	Trauma	Orthotist/ prosthetist	RAF
Zavier	75	Man	No	Kenevo	Vascular	Retired	Self
Stephen	46	Man	Yes	Genium	Trauma	Unemployed	RAF
Taylor	26	Woman	Yes	Genium	Trauma	Student	RAF
Thomas	25	Man	Yes	Rheo XC	Trauma	Own business	RAF

Themes: Five themes with subthemes were identified inductively from the data, as shown in Table 2 below. These included: A life of quality – "life-changing"; Functional ability – "the beauty is it helps you perform properly"; Safety – "a few stumbles but every time the knee catches me"; Limitations – "sometimes the mechanics are a little bit slow"; and Obtaining an MPK.

Table 2. Themes and subthemes identified from the data

Theme	Subthemes
A life of quality – "life-changing"	• Normalising • Socialising
Functional ability – "the beauty is it helps you perform properly"	• Walking distances • Activity levels • Hands-free • Negotiating different obstacles • Exercise
Safety – "a few stumbles but every time the knee catches me''	• Secure • Forgiving • Dependent on working order
Limitations – "sometimes the mechanics are a little bit slow''	• Reaction time • Not waterproof • Weight and size • Battery life
Obtaining an MPK	• Funding • Motivation • Waiting time

3.1 Theme 1: A life of quality – "life-changing"

Participants were enthusiastic about the MPK. Phrases like "it is almost human" (Zavier), and "it is limitless, incredible" (Stephen), reflected their positivity. They associated feelings of freedom, victory, invincibility, power, confidence, joy, and hope with the MPK. The prosthesis with MPK allowed participants to walk without crutches. When not wearing the prosthesis and having to use crutches for mobility they felt somehow diminished; disabled and unsafe.

> Stephen explains further: "It really, really changed my life. It brought me back to as close as I could possibly be before the accident … I won't be able to function normally without the leg now. If I have crutches, I am disabled. When I have the leg on, I am normal."

This connection of the prosthesis with an MPK to *normality* and how it seamlessly links with the body's movements are further shown by Taylor, stating: "Well, if I take my leg off, then I feel unsafe on the crutches; I prefer to use my prosthetic leg because it feels so good and normal. It feels very natural … I just enjoy the movement and how my body moves with it."

Participants described how their lives changed since being introduced to an MPK. These changes ranged from improved function and mobility through decreased secondary complications to financial independence. Stephen alluded that the functionality of the MPK in comparison to NMPKs and crutches is "life-changing" and made him feel invincible.

> Stephen: "The functionality is incredible … it is life-changing … before this leg, being on crutches, I actually had to go to a physio to help my back. I had excruciating pain, and ever since I have been on this leg, it is gone … at this stage, I almost feel like the terminator."

Thomas who owns his own business making leather bags and other products said:

> "I have a successful business now. Some of the credit I get is due to the leg. I love it. I mean, it is my life. It makes me mobile. It makes things happen. I walk my dogs, which is something I like to do."

Participants did not experience social anxiety about wearing the prosthesis with the MPK and felt no need to hide it in public.

> Thomas: "The leg that I have now has helped me emotionally because it's a very beautiful leg; it made me come out of my bubble; I was a bit shy. I would try to hide my other leg, wear long pants. With this one, I don't do that anymore. I will only wear long pants if it is very cold. And when people comment on this beautiful leg, you end up finding disability being a cool thing."

Some participants described an increase in confidence related to *social life* because they felt more confident about moving around with the MPK.

> Stephen: "With being on the crutches, even with the previous prosthesis, I didn't want to get out. I felt very unsafe because you can slip on wet surfaces. So, it really limited

> me a lot when it came to the social aspect of life. Now with this leg, I can't wait to get out."

Other participants had different experiences:

> Taylor: "In the beginning, I was quite sociable, especially when I had my wheelchair, and then I got to a point when I had my prosthetic where I was quite cautious about where I went because when I go somewhere, I think about where I am going and what the terrain is – Is there parking?, Are there stairs?, How is everything situated…There were a lot of times that I wouldn't go out because I wasn't sure who would be there and what the settings were. But I have become a lot more confident in going out now by myself and going to the shop or meeting up with someone and finding parking, but it is still a thing.''

3.2 Theme 2: Functional ability – "the beauty is it helps you perform properly"

The ages and types of activities performed by participants varied. Employment and chosen leisure activities placed different physical demands on participants. Participants emphasised the importance of walking and their ability to walk considerable distances during a typical day (with step counts varying between 3 000 and 10 000 steps per day, which participants were able to track on their phone or watch devices).

The narratives of two participants similar in age and with different activity levels showed the versatility of MPKs. Jeannot described how his prosthesis activities have changed over the years as he went from a highly active job to being retired. Being a tour guide, he was often on and off buses and in and out of hotels with many people following him. Now retired, he is still active through gardening and household chores. Zavier described a different scenario, "I can walk at this moment with the aid of a walker. I have not yet graduated onto using crutches." He was convinced that the MPK was the best choice for him as it can be programmed to provide

less stability as he improves gradually. He further stated that, “When I got the leg, he [prosthetist] put it onto stage one, which was very, very stiff. I got used to the leg; he reduced it to the next stage. Now I am on stage three or C, and now when I walk, it looks like a normal gait. In the beginning, it was hard to master, but the beauty about this leg is that you have got a computer control that controls the movements of the servers, and in doing that, it helped me from nothing to being able to walk almost as normal.”

Participants enjoyed having their *hands free* to perform tasks while walking or standing.

> Stephen: “Just being able to have two arms free and use your hands. With a prosthetic leg that’s not working well, you still need one crutch, so both hands can’t be free. The biggest change for me was the ability to have both arms free and trust the leg enough that you don’t worry about dropping stuff. So that was one of the biggest, small miracles.’’

Lifting and carrying objects did have limits and depended on variables such as the length of the residual limb and what kind of activities participants were performing.

> Ettiene: “So, I have a very short stump, which does limit my functionality a bit. I can probably pick up around forty kilograms. I can pick it up, no problem, but walking with that is difficult.”

A big challenge when walking with a prosthesis is *negotiating different obstacles*. Not all participants were similarly confident on hills and stairs.

> Thomas: “It (MPK) helps a lot, especially downhill. I can go downhill well and up the stairs as well.”

> Taylor: “Stairs, my physio and prosthetist did show me how to walk downstairs as a normal person would, but I don’t feel safe that way. One foot per step, but I was not comfortable walking that way … I do two feet per step.”

Participants exercised in various ways, including walking and going to the gymnasium.

> Thomas: "I go to my coach on most mornings … I go to the field and train in Stellenbosch. I can do everything that a person can do except for running."

Most participants raised this inability to run with the MPK and the desire to be able to do so.

3.3 Theme 3: Safety – "a few stumbles but every time the knee catches me"

The MPK gave participants a feeling of *security* that they did not have with other prosthetic knees. This is important as falling is, in Taylor's words, "probably the worst thing that could ever happen when you are an amputee."

> Stephen: "I actually preferred not to walk with that leg [prosthesis with an NMPK] because it felt unsafe."

According to participants, stumbling was often a result of inattention and lack of sensation. In these situations, the MPK seems to be *forgiving* and assisted them in preventing a fall.

> Taylor: "I have tripped over carpets, but it has never been because there's a fault with the leg with the [MPK] … or if I am a bit lazy and not focusing on my walk and then I will release too much pressure off the knee, and it will buckle, and I will almost fall, but I have gotten used to it."

However, the safety of the MPK was dependent on being in *working order, and the battery having power, and the user being educated on the functioning of the knee.* Data showed that users might have needed more education re the functioning of the knee to ensure their safety.

> Ettiene: "I fell a lot early this year until I understood what was happening with the leg. I had been using it for three years and then started falling. I realised when I took it in [prosthetist] that a lot of things were damaged in the knee. So, I could not balance."

> Taylor: "I had falls with the first [MPK] I had because when it went flat, it stopped working. I was very new, so I just feel like it didn't give me enough warning, and I wasn't prepared. I didn't know it would not lock if it went flat."

3.4 Theme 4: Limitations "Sometimes the mechanics are a little bit slow"

Aspects related to the MPK that participants identified as limitations included its lack of waterproofness, reaction speed, battery life, weight, and size. MPKs have some water resistance, which participants found to be a benefit. Still, there was some reluctance to use the prosthesis with an MPK in situations where it might get wet.

> Taylor: "I have a waterproof prosthetic as well, and that is not an MPK. I went to Bali and took the waterproof one, and I fell twice because it is not as safe. What I am getting at is that I wish they made a safe MPK waterproof knee."

> Jeannot: "You know it doesn't matter if you have to walk to your lawn and the sprinkler is on. As long as you don't submerge it for an hour, then nothing will happen. So that is quite a big benefit."

The lag in reaction speed of the MPK was also pointed out. This experience might be due to incorrect settings, but has not been explored further:

> Jeannot: "Sometimes the mechanisms are a little bit slow with the electronic knee when it has to lock."

Participants acknowledged the increase in weight.

> Ettiene: "The weight adds quite a big difference, but the benefits like the safety of the knee outweigh that."

The size of the MPK was noted, especially where the residual leg was long:

> Stephen: "They amputated about 10cm above the knee. So now, with the socket and the knee fitted, the knee does not line up well with my normal leg."

A rather short battery life in some MPKs (a day) and a lack of a replacement battery was seen as a limitation.

> Jeannot: "The only thing with the [his first MPK] is that the battery was relatively small … Unfortunately, there was no spare battery you could take with. The [his current MPK] also does not have [a spare battery], but it lasts for three to five days – much better."

3.5 Theme 5: Obtaining the MPK

As shown in Table 1, the RAF funded the MPKs for all but two of the participants. One was self-funded, and it seems as if the expense made a substantial dent in the participant's savings.

> Zavier: "Medical aid paid for very little … the rest I had to delve into my savings and pay for it … so that part cleaned me out of my savings. So I have got to live carefully. I do understand that not a lot of people have this opportunity, and hopefully, medical aids will eventually come around."

Claimants have the option to claim through an attorney or directly from the RAF. RAF claims are a legal process, and it is for this reason that there may be a delay of several years before the undertaking is issued. The process thereafter is quicker, usually a waiting period of a few months to get final approval for specific prosthetic components.

> Stephen: "They [the attorneys] employed a private investigator to sort it out [the accident report] … it took me about three years before it was eventually given the okay that RAF would accept 100% liability and said they would cover all the costs … approval for the quote took about three months."

4. Discussion

A primary reason for providing prostheses is to compensate for the loss of function and enhance independence, therefore, enabling persons with a disability to participate in all aspects of their lives (De Witte, Steel, Gupta, Ramos & Roentgen, 2018). This research study's results show that a prosthesis with an MPK, compared to a NMPK, indeed enabled individuals with a disability to improve their function and enhance their independence, integrating them into their communities through pursuits in education, employment, and leisure activity. These individuals were integrated into their communities and pursued educational, employment and leisure activities. Participants that wore NMPKs previously felt that the MPK increased their functional abilities. However, that does not mean that another NMPK design could not have assisted them with similar achievements. No information was gathered on the rest of the prosthesis, such as socket design, suspension system, ankle, or foot components, of which all can impact function with the prosthesis. The qualitative results concur with previous quantitative findings that MPKs increase both function and the quality of life of prosthetic users compared to NMPKs (Berry et al., 2009; Stevens & Wurdeman, 2019).

Participants in a qualitative study conducted by Jefferies, Gallagher and Philbin (2018:1756) expressed the notion that a prosthesis should allow them to be *normal*, meaning walking "in a way they perceive is right". In this research study, participants referred to themselves as being 'normal' when wearing the prosthesis with the MPK and 'disabled' without it. This normalising ability of prostheses with appropriate components together with the positive effect it has on the well-being of the individual, has been well explored by Buetow, Martínez-Martín and McCormack (2019).

The social anxiety so often associated with limb loss and other impairments (Desmond & MacLachlan, 2002; Jefferies et al., 2018) was not noted amongst these participants when using the MPK, but was present with the NMPK. It is important to note that aesthetics is one of the

primary needs that should be met as the prosthesis might not be worn if the user does not find it aesthetically acceptable (Hall & Orzada, 2013).

Previous findings from South Africa on prosthetic use and walking distances with a prosthesis vary. Ennion and Manig (2019) found in a qualitative study that users (n = 9) who received prostheses from a government centre in Mpumalanga (no information on prosthetic components were provided, and three of the nine participants used transtibial prosthesis) that, similar to this research study's findings, participants wore their prosthesis daily, and can walk long distances with it. On the contrary, a quantitative study done in the Western Cape public sector, where participants (n= 43; mean age 55.2 years) received single-axis mechanical knees, found that 42% of transfemoral prosthetic users reported daily prosthetic use, and 5% were able to walk 1 000 steps or more at a given time before rest was needed. This does not reflect the total distance walked in a day (Pienaar & Visagie, 2019). Additionally, 83% of the participants relied on crutches when walking with the prosthesis. Reasons given for nonuse of the prosthesis included fear of falling, not understanding how to use the prosthesis, and that the prosthesis was heavy and tiring to walk with.

An advantage of the MPK emphasised by current participants was its safety features and ability to recover effectively even when stumbling occurred. Other studies have also found a decrease in falls and less fear of falling among users of MPKs (Berry et al., 2009; Fairley, 2014; Hafner et al., 2007; Kaufman, Levine, Brey, McCrady, Padgett & Joyner, 2008; Morgenroth, 2013). In instances where current participants did experience knee failure they were surprised if not shocked by it. Knee failure was usually due to battery life or the knee being in need of maintenance. It is possible that participants were not sufficiently trained on what to expect re batery life and the maintenance requirments of the knee. One reason for the nonuse of transfemoral prostheses is safety (Pienaar & Visagie, 2019). Falling with a prosthesis creates

fear in the user (Miller, Speechley & Deathe, 2001), decreasing confidence during functional activities (Felcher, Stinner, Krieger, Wilken, Gajewski & Hsu 2015).

The improved walking ability and security, as well as not being dependent on a crutch/es when walking with the prosthesis, resulted in further functional gains. Participants had their hands free, could carry objects and perform tasks while standing and walking. Haffner et al. (2007) also described the ability to multitask when using an MPK.

The user must understand an MPK to function as it was intended to (Morgenroth, 2013). Users must be well trained in the mechanical aspects of walking with the knee and the technological requirements of maintaining the knee, such as charging batteries, which is why it is important to note the negative experience of having the battery go flat and two of the participants not knowing that the MPK would then perform like a NMPK. The battery did not last as long as participants would like, and having a spare battery or a car charger would be a benefit. This, unfortunately, does not yet exist on the market.

Some participants felt that the mechanisms were a bit slow to react to changes in walking. This can be problematic for highly active users who want to move quickly and do not have time to wait for the leg to process changes in walking speed, cadence and support surfaces. It might also be that the settings of the knee needs changing to fit the individual users functional requirements. No research could be found on this topic.

There is only one waterproof MPK on the market (Genium X3) and, as such, also comes at the highest cost. Certain lines of employment or extreme weather conditions would then be a contra-indication for prescribing a prosthesis with an MPK. The participants noted the increased weight of the MPK but reported that the benefit of the MPK outweighs this concern. The added weight may be a contra-indication for users that do not have sufficient strength to accommodate the extra weight.

The cost of MPKs inhibits their use in South Africa. In addition, the prescription of technologically advanced prosthetic knees, such as MPKs, is limited in developing countries due to limited access to maintenance services (Ennion & Manig, 2019; Wyss, 2015). An MPK needs to be properly maintained if it is to be used safely (Wyss, 2015). In the rural South African context, prosthetic knees must be durable and repairable (Wyss, 2015).

The various prosthetic knee designs all have advantages and disadvantages, although research suggests that MPKs have superior qualities (Berry et al., 2009; Fairley, 2014; Hafner et al., 2007). These superior qualities come at a substantial financial cost. The provision of assistive products, including prosthetic knees, must be sustainable in a country (WHO, 2017). Thus, it is unrealistic to recommend that all, or most, South African prosthetic users have access to an MPK. Polycentric and hydraulic knees are more affordable options. Also, according to Wyss (2015), the optimal prosthetic knee has not yet been designed.

The South African RAF funds MPKs, but often after arduous legal processes and long waiting times. Long waiting times can lead to problems such as the development of poor gait patterns and psychological resistance against prosthetic use. The process includes going to court to determine if the claim is valid. Future loss of income (occupational) is calculated, the undertaking certificate is issued, and the amount for the loss (of the limb) is calculated. Future loss and damages will be paid out in monetary value, and the rest is in the undertaking, which will cover medical costs. The RAF process is lengthy because there are no policies in place for the prescription of prosthetics. Litigation takes long as there are no linear processes. After a quotation for a prosthesis is provided, a case manager is assigned to evaluate the user and recommend approval/disapproval of the prescription and quotation.

In this study, one participant funded the MPK himself. This gentleman sauntered indoors. He was convinced that buying the MPK was the right thing for him. His assertion that the MPK enhances stability and walking function is supported by findings from Eberly, Mulroy,

Gronley, Perry, Yule and Burnfield (2014). However, spending all your savings on being able to walk slowly indoors when a wheelchair could provide faster and safer mobility at a fraction of the cost seems irrational.

5. Conclusion

Current participants benefited functionally, emotionally and economically from having an MPK. As such this study juxtapose the positive experiences of a small group of participants against a very high financial cost of a MPK in the context of a LMIC. While not everyone would benefit from a specific design in the same way, the study results suggest that an MPK should be considered more often as an option in South Africa. Choosing a prosthetic knee depends on user function, life roles, environmental requirements, and financial resources availability. Successful ambulation does not depend on the latest or most expensive technology but rather on user comfort, function, safety, and acceptable aesthetics, and device maintenance.

6. Recommendations

- It is recommended that government and medical insurance companies entertain the option of prescribing an MPK in specific instances where it can assist the user in obtaining considerable functional and participation benefits not possible with other knee designs. However, current results are not sufficient to identify the specific instances that would support MPK prescription, and more research is necessary in that regard in South Africa.
- It is recommended that professionals provide more education to users on MPKs when fitting a prosthesis with such technology. This will improve users' understanding of how the knee functions so that they can achieve optimal function and prevent unnecessary falls.
- The provision of a spare battery, car charger and/or power bank is recommended.
- A change in the RAF procedures that can speed up the process of getting approval is recommended.

- Research on the direct and indirect economic benefits of MPKs in lower-middle-income countries (LMIC) is recommended.
- Research into the reaction speed of MPKs to changing walking patterns and/or support surfaces is recommended.
- Further research into developing a functional, safe, cost-effective prosthetic knee that suits conditions and user needs in LMIC is recommended.

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Appendix A: Informed consent form

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF RESEARCH PROJECT:	
A qualitative exploration of the experience of using an above-knee prosthesis with a microprocessor knee	
DETAILS OF PRINCIPAL INVESTIGATOR (PI):	
Ms Tosca Strafella	**Ethics reference number:** **S19/10/248**
Full postal address: Rondebosch Medical Center 106, Summit house, First floor (85 Klipfontein Road, Mowbray, 7708)	**PI Contact number:** **062 437 5221**

I would like to invite you to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask me any questions about any part of this project that you do not fully understand. It is very important that you are completely satisfied, clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary,** and you are free to decline to participate. In other words, you may choose to take part, or you may decide not to take part. Nothing bad will come of it if you say no: it will not affect you negatively in any way whatsoever. Refusal to participate will involve no penalty or loss of benefits or reduction in the

level of care you are otherwise entitled to. You are also free to withdraw from the study at any point, even if you do agree to take part initially.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University.** The study will be conducted according to the ethical guidelines and principles of the International Declaration of Helsinki, South African Guidelines for Good Clinical Practice (2006), Medical Research Council (MRC) Ethical Guidelines for Research (2002), Department of Health Ethics in Health Research: Principles, Processes and Studies (2015), **and will follow guidelines set out by the Faculty of Medicine and Health Sciences surrounding the Covid-19 pandemic (2020).**

What is this research study all about?

- This study will be conducted at home via video calls. A total number of between 6 and 12 people will be asked to participate. Each participant will be interviewed separately.
- This study aims to understand the experiences you have with your prosthesis, focusing on the microprocessor knee you are using. I would like to understand your life with your prosthesis, how you feel about it and how you use it. It is important for practitioners to understand this in order to improve our service to you.
- I will be interviewing you in the comfort of your home via video call. We will set a date and time, and any data used will be compensated for. Depending on the amount of information you have for me, the interview will last between 30–45 minutes.
- I might phone you to ask further questions at a later date.

Why do we invite you to participate?

- You have been invited to participate because you are using a microprocessor prosthetic knee. I think you will be able to give me important information about the prosthesis.

What will your responsibilities be?

- To participate in an informal 30 – 45min semi-structured interview via video call on the appointment date and share your experiences as honestly as possible.

Will you benefit from taking part in this research?

- Hopefully, the information received during this study will highlight the benefits of using a microprocessor knee and help practitioners understand ways to improve prosthetic services. This will likely benefit you and other prosthetic users in the future.

Are there any risks involved in you taking part in this research?

- There are no physical risks in taking part in this research study. You may feel emotionally vulnerable to answering certain questions. This is not intentional, and if you feel this way, you do not need to answer the question. If some of the questions leave you feeling unhappy and you would like counselling, it will be arranged.

If you do not agree to take part, what alternatives do you have?

- You do not have to agree to take part in the study.

Who will have access to your medical records?

- No one will have access to your medical records. Your medical records will not be needed for the purpose of this study.

Even though it is unlikely, what will happen if you get injured somehow because you took part in this research study?

- Should you experience emotional distress during the interview, a counsellor will be made available at no cost to you.

Will you be paid to take part in this study, and are there any costs involved?

- You will receive 1GB of data prior to the video call. Please check your data balance before and after the call. Any further expenses incurred will be fully compensated.

Is there anything else that you should know or do?

- If you have any further questions, please contact me on 062 437 5221 or my supervisor, Dr Surona Visagie, on 082 730 8790 or suronav@sun.ac.za
- You can phone the Health Research Ethics Committee at 021 938 9677/9819 if there is something that the researcher did not explain to you or if you have a complaint.
- You will receive a copy of this information and a consent form for you to keep safe.
- I will keep all records stored safely.

Declaration by participant

By signing below, I, ……..……., agree to take part in a research study entitled: **A qualitative exploration of the experience of using an above-knee prosthesis with a microprocessor knee**

I declare that:

- I have read this information and consent form, or it was read to me, and it is written in a language in which I am fluent and with which I am comfortable.
- I have had a chance to ask questions, and I am satisfied that all my questions have been answered.
- I understand that taking part in this study is **voluntary,** and I have not been pressurised to take part.
- I may choose to leave the study at any time, and nothing bad will come of it – I will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished if the study doctor or researcher feels it is in my best interests or if I do not follow the study plan that we have agreed on.

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2020.

....

Signature of participant **Signature of witness**

Declaration by investigator

I *(name)*, ……..……, declare that:

- I explained the information in this document in a simple and clear manner to ……..
- I encouraged him/her to ask questions and took enough time to answer them.
- I am satisfied that he/she completely understands all aspects of the research, as discussed above.
- I did/did not use an interpreter. (*If an interpreter is used, the interpreter must sign the declaration below.)*

Signed at (*place*) .....…..……. on (*date*) ……...…….. 2020.

....

Signature of investigator **Signature of witness**

Appendix B: Interview questions

Demographic information

Age: _____

Gender: _____

Prosthesis with microprocessor knee received (year): _____

Other prosthetic components:

- Socket design
- Suspension method
- Prosthetic foot model
- Is there a cosmesis?

Cause of amputation: _____

Employment status: _____

Occupation before amputation: _____

Occupation after amputation (if applicable): _____

Interview guide

A qualitative exploration of the experience of using an above-knee prosthesis with a microprocessor knee

Tell me about your life with a prosthesis containing an MPK.

- What role does the prosthesis and MPK play in your life (function, cosmetic, career)?
- What are you able to do with it?
- What can you not do with it?
- Daily activities (up and down stairs? Carrying objects? Inclined/declined walks?)
- How does the MPK help you do things?
- How does the MPK hinder your activities?

How do you feel about your prosthesis and the MPK?

- What do you like about the MPK?
- What do you dislike about the MPK?

Are your prosthesis and the MPK important to you?

- Why/why not?
- Can you explain what changes you would make to your prosthesis?
- Explain how you felt when you could go home with your prosthesis and show your family and friends.
- What experience have you had with others' reactions to you wearing a prosthesis?

Tell me about the MPK

- Explain your need and want to receive an MPK.
- What were some of your expectations for the MPK, and were these met?
- What prosthetic knees have you used prior to the MPK?
- What differences can you describe while adjusting to or using the MPK vs the NMPK?
- Is there anything you can do now with the MPK you did not feel comfortable doing previously?
- Was receiving the MPK a long process, and was funding a problem?
- What are other challenges you faced while getting approval for the use of this knee?
- What would you say to those that have the opportunity to use an MPK but are unsure?
- What is your message to the funders of these devices?
- Explain how you feel about the weight and look of the MPK.

Participants will be given the opportunity to ask/add anything they feel was not covered. Thank the participant for his/her participation and remind him/her that you might phone with follow up questions.

Appendix C: Approval letter

Amendment: 14/08/2020

Project ID: 12941

Ethics Reference No: S19/10/248

Project Title: A qualitative exploration of the experience of using an above-knee prosthesis with a microprocessor knee

Dear Miss Tosca Strafella

We refer to your amendment request and the response received on 29/07/2020.

The Health Research Ethics Committee (HREC) reviewed and **approved** the amendment, as well as the amended documentation, through an expedited review process.

Where to submit any documentation

Kindly note that the HREC uses an electronic ethics review management system, *Infonetica*, to manage ethics applications and the ethics review process. To submit any documentation to HREC, please click on the following link: https://applyethics.sun.ac.za.

Please remember to use your project ID 12941 and ethics reference number S19/10/248 on any documents or correspondence with the HREC concerning your research protocol.

Yours sincerely,

Mrs Melody Shana

Coordinator: Health Research Ethics Committee 1

National Health Research Ethics Council (NHREC) Registration Number: REC-130408-012 (HREC1)·REC-230208-010 (HREC2)

Federal Wide Assurance Number: 00001372

Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number: IRB0005240 (HREC1)·IRB0005239 (HREC2)

The Health Research Ethics Committee (HREC) complies with the South African National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research established by the *World Medical Association (2013). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; South African Department of Health (2006). Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2nd Edition)*; *as well as the Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2nd Edition). The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.*